

REMARKS

Reconsideration of the allowability of the present application is requested respectfully.

Status of the Claims

Claims 2, 4, 6, and 7 to 30 were acted upon by the Examiner in the Office Action dated December 28, 2005. Claims 7, 8, and 11 have been rejoined. Claims 7, 8, 11, 13, and 14 have been amended. Claims 9, 10, 16 to 18, and 23 to 30 have been cancelled. Accordingly, Claims 2, 4, 6, 7, 8, and 11 to 15, and 19 to 22 are presented for examination.

Claims 7, 8, and 11 have been amended to depend from allowed Claim 4.

Claims 13 and 14 have been amended for clarity. No new matter has been added to the application.

Arguments

In response to the Examiner's Office Action, dated December 28, 2005, and Advisory Action, dated May 4, 2006, Applicants respectfully traverse the Examiner's rejection of Claims 7, 8, 11, 12, 13, and 19. Applicants respectfully acknowledge the allowance of claims 2, 4, 6, 14, 15, and 19 to 22.

Claims 12 and 13 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention.

Claim 12 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Examiner states that it is not clear how the DNA is complexed to the peptide.

Applicants respectfully traverse the rejection.

Page 12, lines 16 to 17, of the application, recites:

"Complexed to", as used herein, includes adsorption, non-covalent coupling and covalent coupling of a MTLIP to an active agent or to an active particle."

In addition, page 26, line 15, to page 27, line 11, of the application, recites:

“Methods used to complex a MTLP to an active agent loaded particle (MTLP-active particle complex) include, but are not limited to, adsorption to the active particle, noncovalent coupling to the active particle; covalent coupling, either directly or via a linker, to the active particle, to the polymer or polymers used to synthesize the active particle, to the monomer or monomers used to synthesize the polymer, and, to any other component comprising the active particle. Further, MTLPs can be complexed to a slow-release (controlled release) particle or device (Medical Applications of Controlled Release, Langer & Wise (eds.), CRC Press, Boca Raton, Fla., 1974; Controlled Drug Bioavailability, Drug Product Design and Performance, Smolen and Ball (eds.), Wiley, New York, 1984; Ranger et al. J. Macromol. Sci. Rev. Macromol. Chem. 23:61, 1983; Levy et al. Science 228:190, 1985; During et al. Ann. Neurol. 25:351, 1989; Howard et al. J. Neurosurg. 71:105 1989).

Methods used for viral based gene delivery systems include, but are not limited to, vectors modified at the nucleic acid level to express a MTLP on the surface of a viral particle and mammalian cells or helper viruses, which express MTLP-virus fusion proteins that are incorporated into a viral vector.”

In view of the above, Applicants submit that the present application teaches a variety of methods for complexing the DNA and peptide. These methods include, but are not limited to, covalent linkage of the DNA and peptide. In view of these passages, Applicants submit that it is clear how one skilled in the art could complex the DNA and peptide.

Claim 13 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. In particular, the Examiner states that “MTLP” must be spelled out and it is not clear how the DNA is in the form of an MTLP-coated liposome.

Applicants have amended Claim 13 to recite “A composition according to Claim 12, wherein the DNA is complexed with a membrane translocating peptide (MTLP)-coated liposome.” Applicants submit that this amendment remedies the clarity issues regarding Claim 13.

Applicants submit that the claims as presently amended overcome each of the Examiner's Section 112, paragraph 2 rejections. Accordingly, Applicants respectfully request that the rejection of Claims 12 and 13 under 35 U.S.C. §112, second paragraph, be withdrawn.

The Examiner has indicated that Claims 7 and 8 would be rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention because they are method claims that do not recite steps.

Applicants have amended Claims 7 and 8 to recite the step of "administering the composition of claim 4". Accordingly, Applicants respectfully submit that amended claims 7 and 8 satisfy the requirements of 35 U.S.C. §112, second paragraph.

The Examiner has indicated that Claim 11 only has support for "rats" and that "the animal" is not supported by the specification.

The Examiner is respectfully directed to page 5, lines 5 to 8 of the application, which states:

"More particularly, the present invention provides a MTLP, a MTLP-active agent complex and a MLTP-active particle complex, wherein the MTLP enhances movement of the active agent or of the active particle into a cell, into and out of an intracellular compartment and across a cell layer in an animal, including a human."

Furthermore, Applicants submit that rats are an accepted animal model system, and by presenting data in a rat model, Applicants should be entitled to claim use of the present invention in animals.

Claim 14 has been objected to due to the recitation of "a peptide". Claim 14 has been amended to recite "the composition according to Claim 2" instead of "the peptide according to Claim 2".

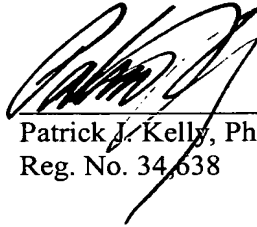
The Examiner has asserted that Claim 19 should be canceled as it is identical to Claim 2. Applicants submit that Claim 2 recites "*comprising* a peptide" while Claim 19 recites "*consisting of*". Accordingly, due to the open and closed nature of the terms "*comprising*" and "*consisting of*", Applicants submit that Claims 2 and 19 are not identical and that Claim 19 should not be canceled.

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Claims 23 to 30 have been canceled without prejudice. Accordingly, rejection of Claims 23 to 30 under 35 U.S.C. §112, second paragraph, is moot.

Respectfully submitted,



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